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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Docket Number (Optional) PRE-APPEAL BRIEF REQUEST FOR REVIEW 1179/214 I hereby certify that this correspondence is being deposited with the Application Number United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for 10/668,801 Sept. 23, 2003 Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] First Named Inventor Ho et al. Signature Art Unit Examiner Typed or printed WEN LIU 3737 Kish, James M. name . Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor. assignee of record of the entire interest. WEN LIU See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) Typed or printed name attorney or agent of record. 32,822 (213) 830-5743 Registration number _ Telephone number attorney or agent acting under 37 CFR 1.34. May 30, 2007 Registration number if acting under 37 CFR 1.34 Date NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PATENT

Docket No.: 1179/214

CERTIFICATE OF TRANSMISSION BY FACSIMILE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.S. Box 1450, Alexandria, VA 22313-1450" on May 30, 2007.

Wen Liu

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Ho, et al.

Serial No.:

10/668,801

Filing Date:

September 23, 2003

For:

RAPID AND NON-INVASIVE

OPTICAL DETECTION OF INTERNAL

BLEEDING

Examiner: Kish, James M.

Group Art Unit: 3737

EXPEDITED PROCEDURE

ARGUMENTS IN SUPPORT OF

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

In connection with the Notice of Appeal to the Board of Patent Appeals and Interferences from the Final Office Action dated January 30, 2007, and the Pre-Appeal Brief Request for Review concurrently filed herewith, Applicant hereby submits arguments in support of such Request.

ARGUMENTS

Applicant set forth detail arguments in the earlier response (Response dated April 30, 2007) concerning the references cited and applied to the pending claims. Applicant incorporates by reference the arguments presented in the earlier response. Applicant will only summarize the arguments herein, and emphasize the deficiencies of the cited references in response to the Examiner's comments in the Advisory Action dated May 14, 2007.

1. The Claimed Invention

The claimed invention is directed to a diagnostic method for detecting specifically internal bleeding in a human body, by detecting the presence of leaked blood at a specific location of the body (claim 1), and a device that is specifically configured to carry out such process (claim 11). This involves illuminating light through a thin layer of tissue that is located at **posterior fornix of vaginal wall** or **rectal wall between the superior and inferior rectal valve**, and analyzing fluorescence emitted from fluorescent compound in leaked blood to diagnose presence of internal bleeding. By analyzing fluorescence emitted from such specifically recited thin tissue regions, one can conveniently detect blood from internal bleeding which is trapped in the abdomen cavity. The detection of said specific tissue region is critical to the invention.

2. Claim Rejections under 35 USC 103

All the pending claims stand finally rejected as being obvious over Chan in view of Haaland et al. Applicant respectfully submits that the combination does not achieve the claimed invention, and there is no apparent reason to one of ordinary skill in the art to combine the teachings of Chan and Haaland in the first place, for at least the reasons discussed below.

a. Combination of Chan and Haaland Does Not Meet Claimed Invention

Chan does not refer to detection of presence of internal bleeding by employing the step of illuminating and transmitting through a thin layer of tissue which is specifically required to be located at the prostinix fornix of vaginal wall or rectal wall between the superior and inferior valves, as required by independent claims 1 and 11. Haaland does not make up for the deficiencies of Chan. Haaland likewise does not specifically refer to such step. Even if one were to refer to Haaland for guidance for internal cavity detection, Haaland simply does not contain an enabling disclosure of the method of detecting through the specific tissue areas recited in claims 1 and 11. Haaland does not recognize the areas beyond those tissue regions where leaked blood may be trapped, much less any enabling disclosure of detecting the presence of blood trapped beyond such tissues. Haaland does not indicate how to undertake detection at those tissue locations, and how its detection instrument may be modified or tuned to implement such detection method. In fact, in the Office Action, at page 2, the Examiner expressly acknowledged that Haaland does not explicitly disclose detecting the posterior fornix of the vaginal wall and the rectal wall area (which are critical areas for purpose of the present invention). Such admission by the Examiner clearly demonstrates that the combination of Chan and Haaland, even if somehow feasible and permissible, would <u>not</u> provide <u>prima facie support</u> to render the claimed invention obviousness. However,

despite such deficiency of the combination, the Examiner nonetheless concluded that the deficiency is obviousness. The Examiner failed to cite an additional reference for such missing teaching, if such additional reference exists in the first place.

Applicant submits that Haaland's general reference to vaginal and rectal areas, absent any specifics, would not render obvious all possible types of detection at all possible tissue areas of the vaginal and rectal areas for all purposes, and specifically the detection through the tissues at the prostinix fornix of virginal wall or rectal wall between the superior and inferior valves required by the pending claims. In the Advisory Action, the Examiner relied on the misguided assertion that: "The tissue thickness requirements would therefore make it obvious to one of ordinary skill in the art to use said apparatus and method at a location adjacent to the abdomen, where internal bleeding is occurring, i.e., the posterior fornix of the rectal wall between the superior and inferior rectal valves." First, even if Haaland is directed to vaginal and rectal examination using its detection instrument, there is no apparent reason from Haaland to detect internal bleeding at the abdomen via vaginal and rectal cavities. Examination of the condition of the vaginal and rectal cavities is different from detection of internal bleeding though the probing of vaginal and rectal cavities. Second, even if it is apparent to a person skill in the art to detect internal bleeding at a location adjacent to the abdomen by probing the vaginal and rectal cavities, it does not necessarily follow that such location would necessarily be specifically the posterior fornix of the rectal wall between the superior and inferior rectal valves, as required by the pending claims. To interpret Haaland to disclose otherwise would be illogical.

By nature of a claim involving a specific process, it would not be proper for the Examiner to simply refer to a reference such as Haaland that teaches nothing more than a possible detection instrument for conducting certain internal cavity detection, in an attempt to find teaching of the specific method defined by the claims of the present invention. To draw an analogy, in the context of claiming a specific novel surgical method for a specific surgical process undertaken at a specific location of the body, the fact that surgical equipments used for such novel process (e.g., surgical knifes) are old in the art, that would not anticipate all possible surgical processes involving specific surgical locations on the human body using such surgical equipment.

Given the foregoing, even if Chan and Haaland can somehow be combined, such combination would not result in an enabling disclosure of detection of internal bleeding comprising detection through specific tissues that are located specifically at the protinix fornix of virginal wall

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or rectal wall between the superior and inferior valve, as required by the independent claims 1 and 11. Even if the references can somehow be combined, it would be necessary to make modifications, not taught in the prior art, in order to combine the documents to obtain the claimed invention.

b. Not Obvious to Combine Chan and Haaland

Applicant respectfully submits that Chan and Haaland should not have been combined in the first place to render the claimed invention obvious, since such combination would not have been obvious to a person skilled in the art. Chan is directed to non-invasive multispectral imaging system that illuminates and detects from external of a person's body (specifically from outside the skin of a person's body, without intrusion into any internal cavity areas of the person, such as rectal and vaginal cavities). Haaland on the other hand is directed to a multivariate classification apparatus that can be used to probe internal of a person's body (specifically inside the cavities in a person's body, such as the cervical areas). Given the diversed purposes of Chan and Haaland, it is clear that neither Chan nor Haaland contain any apparent reason (express or implied) that they be combined by modifying Chan with Haaland, much less that they be combined in any specific manner to obtain the claimed invention, and certainly not in the manner suggested only by the Examiner (which can only be made possible with the benefit of hindsight reconstruction given the disclosure of the present invention).

Chan is complete and functional in itself, so there would be no apparent reason, and in fact no reason has been stated in Chan, to modify its specific teaching of external, through the skin detection with the internal cavity probe detection of Haaland. Chan and Haaland take mutually exclusive paths and reach different solutions to different problems that the respective references address. Chan requires external through the skin detection. Haaland on the other hand requires internal cavity detection. Chan does not contain any apparent reason that its external detection can and should be modified to internal cavity detection. There is no indication anywhere in Chan that internal cavity detection can and should be adequately substituted for its non-invasive external through the skin detection. Further, Chan does not include any apparent reason to refer to another reference for guidance on substituting or modifying its external through the skin detection scheme. There is therefore no apparent reason, taking into account only knowledge which was within the level of ordinary skill at the time the invention was made, if and how Chan could be modified by any reference on internal cavity detection, much less Haaland, while maintaining the non-invasive external through the skin detection that Chan proposes. Such modification is only possible with

impermissible hindsight reconstructions, made possible only by the disclosure of the present invention. Chan therefore effectively teaches away expressly, or at least by implication, from internal cavity detection suggested only by the Examiner by hindsight reconstruction after gleaning the disclosure of the present invention.

Until the creation of the present invention, none of the prior art detection process has been successful to detect internal bleeding in a quick, simple, cost effective manner. The results achieved by the invention are new, unexpected, superior, critical, and unsuggested by any prior art. The present invention provides an enabling solution to a long felt, long-existing, but unresolved need, achieving advantages beyond what the prior art has to offer, and expects to attain commercial success. The accomplishments of the inventors of the present invention involve no small steps. (However, even if the steps taken by the inventors is deemed to be small, the invention is classified in a crowded art; therefore even if a "small" step forward should be regarded as significant.) If the present invention were in fact obvious, because of its advantages, those skilled in the art surely would have implemented it by now. That is, the fact that those skilled in the art have not implemented the invention, despite its great advantages, indicates that the combination suggested in the Office Action would not have been obvious.

3. Conclusion

Accordingly, the present invention is patentable over Chan and Haaland.

Respectfully submitted,

Dated: May 30, 2007

Registration No. 32,822

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